REMARKS

I. <u>Objection to Claims 17-51 under 35 U.S.C. § 132</u>

The Office has declined to consider claims 17-51 "because the amendments filed January 10, 2008 are objected to under 35 U.S.C. 132(a) because it introduces new matter into the disclosure." Office Action, page 2. According to the Office, "[t]he added material which is not supported by the original disclosure is as follows: "A gelled cuture [*sic*, culture] . . . an antibiotic added to the medium before the medium gels, wherein the antibiotic . . . ." The Office requires Applicants to cancel the "new matter." *Id.* Applicants traverse.

Applicants respectfully submit that an objection to claims under Section 132 for new matter is improper. The disputed language was entered only into the claims by amendment, and not into the specification. If the Office believes the amendment entered new matter into the claims, then it should have rejected the claims under the written description requirement of 35 U.S.C. § 112, first paragraph. *See* M.P.E.P. §§ 706.03(o) and 2163.01. Even if the Office were correct and the amendment entered new matter into the claims, the Office must nonetheless consider the amended claim language in considering patentability. M.P.E.P. § 2163; part III. There is no basis in the regulations, nor the M.P.E.P., for not considering the claims.

Moreover, there is written description support in the specification for the claim language entered by the amendment. In paragraph [0001] of the published specification, Applicants describe their invention as "relat[ing] to a novel **<u>gelled</u>** medium for detecting meticillin-resistant microorganisms . . . ." (Emphasis added.) In paragraph [0013], Applicants state that "[t]he media according to the invention make it possible to detect meticillin-resistant bacteria using **<u>an inoculum streaked on a dish</u>**, whereas the

majority of the methods of the prior art use a deposit of approximately 10^4 to 10^5 bacteria on the agar." (Emphasis added.) To streak an inoculum on a medium in a dish the medium must, consistent with the broad description of the invention in paragraph [0001], be gelled.

During a telephonic interview between Examiner Lilling and the undersigned on March 13, 2008, the Examiner questioned whether one of skill in the art would understand that agar, as disclosed in the specification, is employed as a gelling agent in culture media. The Examiner requested that Applicants provide some evidence in the prior art to establish that point. Applicants traverse the requirement for evidence as the specification provides full written description support for the claim language at issue. Nonetheless, solely to advance prosecution, Applicants submit as Exhibit 1 two pages from "The Microbial World" by Roger Stanier et al., which was published in 1976. In discussing the use of plating methods for isolating pure cultures of microorganisms, the authors that "[t]his [plating] method involves the separation and immobilization of individual organisms on or in a nutrient medium **solidified with agar or some other appropriate jelling agent**." (Emphasis added.) Applicants submit that at the time of the invention one of skill in the art would understand that agar was used as a gelling agent in microbiological media.

Support for adding the antibiotic before the medium has gelled is found throughout the specification. For example, in paragraph [0030] the Applicants describe a medium prepared with cefmetazole at a concentration of 2.5 mg/l "added to the medium when the latter is at a temperature of 48° C[,]" that is, before the medium has gelled. Furthermore, in Example 1, paragraph [0060], the specification teaches that

"cefoxitin (5 mg/l) [is] added to this medium, after autoclaving, before the medium is solid (when it is at a temperature of approximately 45° C."

For these reasons, Applicants request that the Office withdraw the objection and examine claims 17-51 on the merits.

II. Requirement for Restriction

The Office has imposed a restriction requirement under 35 U.S.C. §§ 121 and 372. The Office contends that the application contains two groups of inventions that are not linked as to form a single general inventive concept under PCT Rule 13.1. Those two groups are:

Group I, claims 52-77, drawn to a method of detecting the presence or absence of methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample from a patient comprising inoculating a medium comprising, among other things, "an antibiotic, wherein the antibiotic is: cefoxitin, cefmetazole, or moxalactam."

Group II, claims 78-98, drawn to a method of detecting the presence or absence of methicillin-resistant *Staphylococcus aureus* (MRSA) in a sample from a patient comprising inoculating a medium comprising, among other things, "an antibiotic, wherein the antibiotic is: flomoxef." Office Action, page 3.

Applicants elect Group I, claims 52-77, with traverse.

Applicants traverse for the following reasons. While the Office invokes PCT Rule 13.1 and the requirement for a single general inventive concept to link the claims (Office Action, page 2), Applicants submit a single general inventive concept does exist between the claims of Groups I and II. As explained in the specification in paragraph [0011], the invention "relates to a medium for detecting meticillin-resistant

microorganisms, comprising, besides nutrients for the growth of said microorganisms, at least one antibiotic chosen from the group of second or third generation cephalosporins, and a chromogenic agent that releases a chromophore after hydrolysis with an enzyme that is active in said microorganisms." All of the claims in Groups I and II fall within this single general inventive concept. The assertion at the bottom of page 3 of the Office Action that "[i]nvention I is patentably distinct from Invention II since the compounds employed are distinct from each other" is incorrect.

The Office also contends there would be a serious search and examination burden if restriction is not required, offering four reasons on page 4 as supporting this contention. In response, Applicants point out that the subject matter of Groups I and II has already been searched. Claim 1, which was substantively examined, recited all four of the antibiotics that appear in the claims of Groups I and II. See, for example, Amendment filed April 30, 2007, page 2. With the Amendment filed January 10, 2008, Applicants merely moved the flomoxef embodiments into a separate group of claims. Thus, the subject matter of Groups I and II has already been searched and the burden postulated by the Office is no burden at all.

Applicants request that the Office withdraw the restriction requirement and continue examination of the subject matter of claims 52-98 in this application. Applicants also request examination of claim 17-51, in view of the arguments in section I above. In the event that the Office maintains the restriction requirement and makes it final, Applicants respectfully request that the Office examine claims 17-36 with elected claims 52-77. Claims 17-36 recite the same group of antibiotics as the elected claims.

III. Requirement to Elect Species

In addition to the restriction requirement, the Office has also imposed a species election requirement. Office Action, page 5. Examiner Lilling provided further explanation of this requirement to the undersigned during the telephonic interview held on March 13, 2008. In particular, the Examiner explained that the requirement was not limited to the claims of Group [Invention] II as indicated. Furthermore, the Examiner provided additional guidance concerning aspects C, D, and E of the requirement set forth on page 6. Based on that clarification, Applications elect, with traverse, the following:

A. cefoxitin;

B. 5-bromo-6-chloro-3-indoxyl-phosphate;

C. not required for the elected invention;

D. not required for the elected invention; and

E. not required for the elected invention.

In addition to making the election, Applicants are also required to "identif[y] . . . the claims encompassing the elected species . . . ." Office Action, page 8. The claims encompassing the elected species include claims 52-66, 69-72, and 74-77.[1]

The Office acknowledges on page 7 that claims 52 and 76 are generic. In the event elected generic claim 52 is found patentable, Applicants request consideration of claims in the application directed to additional species. *See* M.P.E.P. § 809.02(a) ("Upon the allowance of a generic claim, applicant will be entitled to consideration of

[1] Unexamined claims 17-28, 31-34, and 36 also encompass the elected species.

claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141.").

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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Dated: March 18, 2008

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Library of Congress Cataloging in Publication Data

Stanier, Roger Y
The microbial world.

Includes bibliographies and index.
1. Microbiology. I. Adelberg, Edward A., joint author. II. Ingraham, John L., joint author.
III. Title.
QR41.2.S775 1976 576 76-3636
ISBN 0-13-581025-6

THE MICROBIAL WORLD, Fourth Edition
R. Y. Stanier, E. A. Adelberg, J. L. Ingraham

Previous editions
by R. Y. Stanier, M. Doudoroff, E. A. Adelberg

Printed in the United States of America

10 9 8 7

PRENTICE-HALL INTERNATIONAL, INC., *London*
PRENTICE-HALL OF AUSTRALIA, PTY. LTD., *Sydney*
PRENTICE-HALL OF CANADA, LTD., *Toronto*
PRENTICE-HALL OF INDIA PRIVATE LIMITED, *New Delhi*
PRENTICE-HALL OF JAPAN, INC., *Tokyo*
PRENTICE-HALL OF SOUTHEAST ASIA PTE. LTD., *Singapore*

2

THE METHODS OF MICROBIOLOGY

As a result of the small size of microorganisms, the amount of information that can be obtained about their properties from the examination of *individuals* is limited; for the most part, the microbiologist studies *populations*, containing millions or billions of individuals. Such populations are obtained by growing microorganisms under more or less well-defined conditions, as *cultures*. A culture that contains only one kind of microorganism is known as a *pure* or *axenic culture*. A culture that contains more than one kind of microorganism is known as a *mixed culture*; if it contains only two kinds of microorganisms, deliberately maintained in association with one another, it is known as a *two-membered culture*.

At the heart of microbiology there accordingly lie two kinds of operations: *isolation*, the separation of a particular microorganism from the mixed populations that exist in nature; and *cultivation*, the growth of microbial populations in artificial environments (culture media) under laboratory conditions. These two operations come into play irrespective of the kind of microorganism with which the microbiologist deals; they are basic alike to the study of viruses, bacteria, fungi, algae, protozoa, and even small invertebrate animals. Furthermore, they have been extended in recent years to the study in isolation of cell or tissue lines derived from higher plants and animals (*tissue culture*). The unity of microbiology as a science, despite the biological diversity of the organisms with which it deals, is derived from this common operational base.

PURE CULTURE TECHNIQUE

Microorganisms are ubiquitous, so the preparation of a pure culture involves not only the isolation of a given microorganism from a mixed natural microbial population, but also the maintenance of the isolated individual and its

progeny in an artificial environment to which the access of other microorganisms is prevented. Microorganisms do not require much space for development; hence an artificial environment can be created within the confines of a test tube, a flask, or a petri dish, the three kinds of containers most commonly used to cultivate microorganisms. The culture vessel must be rendered initially *sterile* (free of any living microorganism) and, after the introduction of the desired type of microorganism, it must be protected from subsequent external contamination. The primary source of external contamination is the atmosphere, which always contains floating microorganisms. The form of a petri dish, with its overlapping lid, is specifically designed to prevent atmospheric contamination. Contamination of tubes and flasks is prevented by closure of their orifices with an appropriate stopper. This is usually a plug of cotton wool, although metal caps or plastic screw caps are now often employed, particularly for test tubes.

The external surface of a culture vessel is, of course, subject to contamination, and the interior of a flask or tube can become contaminated when it is opened to introduce or withdraw material. This danger is minimized by passing the orifice through a flame, immediately after the stopper has been removed and again just before it is replaced.

The *inoculum* (i.e., the microbial material used to seed or inoculate a culture vessel) is commonly introduced on a metal wire or loop, which is rapidly sterilized just before its use by heating in a flame. Transfers of liquid cultures can also be made by pipette. For this purpose, the mouth end of the pipette is plugged with cotton wool, and the pipette is sterilized in a paper wrapping or in a glass or metal container, which keeps both inner and outer surfaces free of contamination until the time of use.

The risks of accidental contamination may be further reduced by performing transfers in a hood or in a small closed room, the air of which has been specially treated to reduce its microbial content.

• The isolation of pure cultures by plating methods

Pure cultures of microorganisms that form discrete colonies on solid media (e.g., most bacteria, yeasts, many fungi and unicellular algae) may be most simply obtained by one of the modifications of the plating method. This method involves the separation and immobilization of individual organisms on or in a nutrient medium solidified with agar or some other appropriate jelling agent. Each viable organism gives rise, through growth, to a colony from which transfers can be readily made.

The *streaked plate* is in general the most useful plating method. A sterilized bent wire is dipped into a suitable diluted suspension of organisms and is then used to make a series of parallel, nonoverlapping streaks on the surface of an already solidified agar plate. The inoculum is progressively diluted with each successive streak, so that even if the initial streaks yield confluent growth, well-isolated colonies develop along the lines of later streaks (Figure 2.1). Alternatively, isolations can be made with *poured plates:* successive dilutions of the inoculum are placed in sterile petri dishes and mixed with the molten but cooled agar medium, which is then allowed to solidify. Colonies subsequently develop embedded in the agar.

The isolation of strictly anaerobic bacteria by plating methods poses special problems. Provided that the organisms in question are not rapidly killed by exposure to oxygen, plates may be prepared in the usual manner and then incubated in closed containers, from which the oxygen is removed either by